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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HOWARD A. KINGSFORD

Appeal 2007-1847
Application 09/440,384
Technology Center 1700

Decided: January 8, 2009

Before BRADLEY R. GARRIS, ADRIENE LEPIANE HANLON, and
CHARLES F. WARREN, *Administrative Patent Judges*.

HANLON, *Administrative Patent Judge*.

DECISION ON APPEAL

A. STATEMENT OF THE CASE

This is an appeal under 35 U.S.C. § 134 from an Examiner's final rejection of claims 2-23, all of the claims pending in the application. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

The following Examiner's rejections are before us for review:

Claims 4, 10, 16, 17, 19-21, and 23 are rejected under 35 U.S.C. § 102(b) as anticipated by Reed.¹ Ans. 3.²

Claims 2, 3, 5-9, 11, 12, 18, and 22 are rejected under 35 U.S.C. § 103(a) as unpatentable over Reed. Ans. 4.

Claim 13 is rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Reed and Fye.³ Ans. 7.

Claims 14 and 15 are rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Reed and Coates.⁴ Ans. 7.

The subject matter on appeal relates to a skin attachment member comprising an array of skin penetrating elements extending integrally from the surface of a backing wherein the array of skin penetrating elements is formed integrally from a single plastic resin.

Claim 19 is the only independent claim on appeal, and it reads as follows:

19. A skin attachment member of plastic resin, comprising:
- a backing, and
 - an array of skin penetrating elements extending integrally from a surrounding surface of the backing to a tip, the skin penetrating elements sized to avoid contact with nerves below the epidermal skin layer,
 - a plurality of the skin penetrating elements each including a retention barb extending from an outer surface of the skin penetrating element,

¹ US 5,312,456 issued to Reed et al. on May 17, 1994.

² Examiner's Answer dated June 8, 2006.

³ US 5,031,609 issued to Fye on July 16, 1991.

⁴ US 4,219,019 issued to Coates on August 26, 1980.

wherein the array of skin penetrating elements, including each retention barb, is formed integrally from a single plastic resin.

Br. 10-11, Claims Appendix.⁵

B. ISSUES

Issue 1: Has the Appellant shown that the Examiner reversibly erred in finding that Reed describes an array of skin penetrating elements formed integrally from a single plastic resin as recited in claim 19?

Issue 2: Has the Appellant shown that the Examiner reversibly erred in concluding that a skin penetrating element comprising a cone-shaped body as recited in claim 2 would have been obvious to one of ordinary skill in the art in view of the teachings in Reed?

Issue 3: Has the Appellant shown that the Examiner reversibly erred in concluding that the parameters recited in claims 5-9, 11 and 12 would have been obvious to one of ordinary skill in the art in view of the teachings of Reed?

Issue 4: Has the Appellant shown that the Examiner reversibly erred in concluding that the combined teachings of Reed and Fye render obvious the subject matter of claim 13?

Issue 5: Has the Appellant shown that the Examiner reversibly erred in concluding that the combined teachings of Reed and Coates render obvious the subject matter of claims 14 and 15?

⁵ Appeal Brief dated August 15, 2005.

C. FINDINGS OF FACT

The following findings of fact are supported by a preponderance of the evidence. Additional findings of fact as necessary appear in the Analysis portion of the opinion.

1. Reed

The invention disclosed in Reed relates to a micromechanical barb. Reed 1:6-9.

Reed Figure 6 illustrates an embodiment of a barb. Reed 2:28-29. Figure 6 is reproduced below:

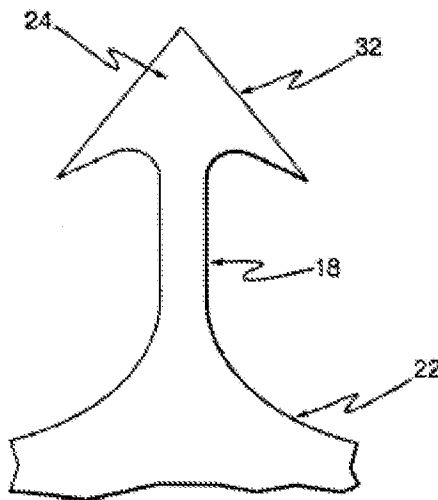


FIG. 6

Reed Figure 6 depicts a barb.

Reed discloses that the base **22**, head **20**, and support **18** are preferably integral with each other. The head **20** preferably has a central portion **24** which is connected to the support **18**. Reed 3:33-36.

Reed discloses that the base **22**, head **20**, and support **18** are made of a rigid material. The rigid material can be, for example, metal, ceramic,

plastic, composite material, or alloy. Reed discloses that the plastic can be polysulfone. Reed 3:39-45.

Reed discloses that the piercing barbs are able to pierce skin or other tissues for medical applications. Reed 4:30-32.

Reed also discloses that sheets of piercing barbs **16** can be used as skin bandages to close incisions or wounds. Reed 5:21-22.

D. PRINCIPLES OF LAW

A claim is anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003).

A presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled. *Id.* at 1355. An applicant bears the burden of rebutting the presumption of enablement by a preponderance of the evidence. *In re Sasse*, 629 F.2d 675, 681 (CCPA 1980).

Enablement requires that the disclosure teach those in the art to make and use the invention without “undue experimentation.” *Elan Pharm., Inc. v. Mayo Found.*, 346 F.3d 1051, 1054-55 (Fed. Cir. 2003); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). A patent need not disclose what is well known in the art. *Wands*, 858 F.2d 735.

Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation

necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.*

A claimed invention is also not patentable if the subject matter of the invention would have been obvious to a person having ordinary skill in the art at the time the invention was made. 35 U.S.C. § 103(a); *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 13 (1966).

Facts relevant to a determination of obviousness include (1) the scope and content of the prior art, (2) any differences between the claimed invention and the prior art, (3) the level of skill in the art, and (4) any relevant objective evidence of obviousness or non-obviousness. *KSR*, 127 S. Ct. at 1734; *Graham*, 383 U.S. at 17-18.

A person of ordinary skill is not an automaton but is a person of ordinary creativity. *KSR*, 127 S. Ct. at 1742. One of ordinary skill in the art is presumed to have skills apart from what the prior art references expressly disclose. *In re Sovish*, 769 F.2d 738, 742 (Fed. Cir. 1985).

E. ANALYSIS

1. Issue 1⁶

The Examiner found that Reed discloses a skin attachment member comprising an array of skin penetrating elements having a pointed shape that can penetrate skin. The Examiner found that the outer surface of the

⁶ The Appellant does not argue that claims 4, 10, 16, 17, 20, 21, and 23 are separately patentable from claim 19.

elements includes a retention barb. The Examiner also found that Reed discloses that the elements are formed of plastic and are integral with a backing. The Examiner found that the plastic comprises a single plastic resin (polysulfone). Ans. 3.

The Appellant recognizes that Reed discloses that “[t]he base **22**, head **20** and support **18** are made of a rigid material.” However, the Appellant argues:

One of ordinary skill in the art, when viewing Reed as a whole, would not understand Reed to have disclosed skin penetrating elements formed integrally of a single material. Instead, taking the above quote in context of the entire disclosure, one of ordinary skill in the art would understand Reed to mean that each of the base, head, and support are made from a rigid material, but not of the same rigid material. [Emphasis in original.]

Br. 5-6.

We disagree. Reed expressly discloses:

The base **22**, head **20** and support **18** are made of a rigid material. The rigid material can be, for instance, metal, ceramic, plastic, composite material *or* alloy. The metal could be steel, the ceramic could be aluminum oxide, the composite material could be graphite fiber matrix composite and the plastic polysulfone. [Emphasis added.]

Reed 3:39-45.

Based on this disclosure in Reed, it is reasonable to find that the base, head, and support can be made of a single rigid material, such as polysulfone. Thus, it is reasonable to find that Reed discloses a skin penetrating element formed integrally from a single plastic resin as required by claim 19.

The Appellant also argues that the disclosure of Reed does not enable one of ordinary skill in the art to make a skin penetrating element formed integrally from a single plastic resin. The Appellant argues that the only manufacturing method disclosed in Reed is a photochemical etching process in which layers of different materials are sequentially etched. The Appellant relies on a Declaration of Andrew C. Harvey dated June 20, 2002, as evidence that the Reed disclosure is not enabling. Br. 4-5.

In the Declaration, Mr. Harvey discusses the process disclosed in Reed for producing barbs wherein the support **18** is formed of Si and the head **20** is formed of SiO₂. *See* Harvey Declaration, para. 6; Reed 6:50-57. Based on this sole example in Reed, Mr. Harvey concludes:

[Reed] in no way teaches or suggests a technique for manufacturing a barb in which the base 22, head 20, including central 24 and extremity portions 26, and support 18 are all formed *integrally of a single plastic resin*. [Emphasis in original.]

Harvey Declaration, para. 7.

A presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled. *Amgen*, 314 F.3d at 1355. The Appellant bears the burden of rebutting this presumption by a preponderance of the evidence. *Sasse*, 629 F.2d at 681. In particular, the Appellant must show that “undue experimentation” would be required to make and use the invention disclosed in Reed. *Wands*, 858 F.2d at 737.

The Harvey Declaration does not discuss “undue experimentation” or present any facts establishing that undue experimentation would be required to form the Reed article integrally from polysulfone. The Declaration merely concludes that Reed does not *teach or suggest* a technique for

manufacturing a barb integrally from a single plastic resin. This conclusion is insufficient to rebut the presumption of enablement by a preponderance of the evidence. *See Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) (nothing in the rules or in jurisprudence requires the fact finder to credit unsupported or conclusory assertions); *In re Brandstadter*, 484 F.2d 1395, 1406 (CCPA 1973) (affidavits reciting conclusions and few facts to buttress the conclusions fail in their purpose).

For the reasons set forth above, the Appellant has not shown that the Examiner reversibly erred in finding that Reed describes an array of skin penetrating elements formed integrally from a single plastic resin as recited in claim 19.

2. Issue 2⁷

The Examiner found that Reed discloses a skin penetrating element comprising a pointed triangular body but does not disclose a skin penetrating element comprising a cone-shaped body as recited in claim 2. Nonetheless, the Examiner found that a change in shape is generally recognized as being within the level of ordinary skill in the art. The Examiner cites *In re Dailey*, 357 F.2d 669 (CCPA 1966), for support. Ans. 5.

In response, the Appellant argues that the recited shape is significant with respect to skin penetration and retention. The Appellant points to page 4, line 15 of the Specification for support. Br. 7.

The Appellant's argument is not persuasive of reversible error. According to page 4, lines 15-16 of the Appellant's Specification, "Cone 18

⁷ The Appellant does not argue that claims 3 and 22 are separately patentable from claim 2. Br. 7.

tapers from a larger diameter proximal base 22 to a distal pointed tip 24.”

The Specification continues:

The skin-penetrating projecting plastic elements 14 can be other than conical in shape. For example, elements 14 can be in the shape of a pyramid, a tetrahedron, or may be elliptical or square in cross-section, tapering to points at their distal ends. Rather than taper distally, elements 14 can progressively step down in diameter. Regardless of the particular shape selected, the elements 14 include sharp pointed tips 24 to ease tissue penetration.

Spec. 4:25-32.

Based on the record before us, we find that the critical feature of the Appellant’s skin penetrating element is the pointed tip. However, Reed also discloses a skin penetrating element comprising a pointed tip that facilitates penetration. Reed 3:60-63.

As for the overall shape of the skin penetrating element, the Appellant has not directed us to any evidence establishing that the recited shape is significant or anything more than one of several shapes that one of ordinary skill in the art would have found useful for supporting the pointed tip.

For the reasons set forth above, the Appellant has not shown that the Examiner reversibly erred in concluding that a skin penetrating element comprising a cone-shaped body as recited in claim 2 would have been obvious to one of ordinary skill in the art in view of the teachings in Reed.

3. Issue 3⁸

The Examiner found that Reed does not disclose a skin penetrating element having the various parameters recited in claims 5-9, 11 and 12.

⁸ The Appellant does not argue that claim 18 is separately patentable from claims 5-9, 11, and 12. Br. 7.

Nonetheless, the Examiner found that it would have been within the skill of the ordinary artisan to vary the parameters of the skin penetrating element depending on the desired end use of the skin attachment member. Ans. 5-6.

The Appellant does not direct us to any evidence of unexpected results. Rather, the Appellant argues that the Examiner has not presented any evidence to establish that the claimed parameters are merely matters of routine optimization or design choice. Br. 7.

The Appellant's argument is not persuasive of reversible error. Claim 5 recites that the skin penetrating element has a length of about 0.012 inch (0.3 mm). Br. 9, Claims Appendix. Reed discloses that the height of the barbs or skin penetrating elements is no greater than 5 mm, and preferably less than 0.5 mm. Reed 3:1-5. We find that this range *prima facie* encompasses the claimed length. As for the remaining parameters recited in claims 5-9, 11 and 12, Reed discloses an embodiment wherein the parameters are smaller than those claimed. *See, e.g.*, Reed 6:11-15.

We find that the Reed device is used for the same purpose as the claimed skin attachment member, i.e., to pierce skin or other tissues for medical applications. Reed 4:30-32. We find that it would have been within the skill of the ordinary artisan to adjust the parameters of the Reed device based on a number of factors, including the area of the body to be penetrated and the elasticity of the skin. *Compare, e.g.*, Spec. 4:1-14. Thus, absent evidence of unexpected results, it is reasonable to find that the claimed parameters would have been within the skill of the ordinary artisan. *KSR*, 127 S. Ct. at 1742 (a person of ordinary skill is a person of ordinary creativity).

In sum, the Appellant has not shown that the Examiner reversibly erred in concluding that the parameters recited in claims 5-9, 11 and 12 would have been obvious to one of ordinary skill in the art in view of the teachings of Reed.

4. Issue 4

The Appellant argues that claim 13 is allowable for the same reasons that claim 19 is allowable. The Appellant does not otherwise dispute the Examiner's findings or conclusion of obviousness as to claim 13. Br. 7-8.

For the reasons set forth above, the Appellant's arguments with respect to claim 19 are not persuasive of reversible error. Thus, the Appellant has not shown that the Examiner reversibly erred in concluding that the combined teachings of Reed and Fye render obvious the subject matter of claim 13.

5. Issue 5

The Appellant argues that claims 14 and 15 are allowable for the same reasons that claim 19 is allowable. The Appellant does not otherwise dispute the Examiner's findings or conclusion of obviousness as to claims 14 and 15. Br. 7-8.

For the reasons set forth above, the Appellant's arguments with respect to claim 19 are not persuasive of reversible error. Thus, the Appellant has not shown that the Examiner reversibly erred in concluding that the combined teachings of Reed and Coates render obvious the subject matter of claims 14 and 15.

F. DECISION

The rejection of claims 4, 10, 16, 17, 19-21, and 23 under 35 U.S.C. § 102(b) as anticipated by Reed is affirmed.

The rejection of claims 2, 3, 5-9, 11, 12, 18, and 22 under 35 U.S.C. § 103(a) as unpatentable over Reed is affirmed.

The rejection of claim 13 under 35 U.S.C. § 103(a) as unpatentable over the combination of Reed and Fye is affirmed.

The rejection of claims 14 and 15 under 35 U.S.C. § 103(a) as unpatentable over the combination of Reed and Coates is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 35 U.S.C. § 1.136(a) (2008).

AFFIRMED

tc

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022